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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/681,303	03/15/2001	Samuel F. Liprie	INE-0044-C2	9542

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EXAMINER

KEITH, JACK W

ART UNIT	PAPER NUMBER
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3641

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/681,303

Applicant(s)

Liprie

Examiner

Jack Keith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 20, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 & 8 6) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of species III, A, a (nickel/titanium alloy), b (titanium) and c (gold) in Paper No. 7 is acknowledged. The traversal is on the ground(s) that none of the species materials are presently claimed. This is not found persuasive. In applications in which no species claims are present and a generic claim recites such a multiplicity of species that an unduly extensive and burdensome search is required an election of species is made prior to a search of the generic claim (see MPEP § 808.01(a)). Furthermore, based on applicant's parent applications and the Office Actions on said parent cases the material species are relevant to the claimed invention.

The requirement is still deemed proper and is therefore made FINAL.

2. No claims are withdrawn at this time as all claims read on the elected species.

Specification

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to provide an adequate written description of the invention and as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Referring to figure 3 it is not clear how and in what manner a flat ended source wire provides for the ease of maneuverability to the treatment site. It would appear that such a blunt end would hinder the maneuverability of the source wire.

Claim Objections

5. Paper no. 6 amended claim 14; however, it appears that the amendment should have been to claim 13. Appropriate correction is required.

Note that amended claim 14 will be treated as claim 13 for the purposes of rejections set forth below. Original claim 14 now canceled will fall under any rejections of claims 2 and 24.

Claim Rejections - 35 USC § 112

6. Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The reasons that the inventions as disclosed are not enabling are the same as the reasons set forth in section 4 above as to why the specification is objected to and the reasons set forth in section 4 above are incorporated herein.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Statements about intended uses, capabilities, or structures which may result upon the performance of future acts (i.e., when bent), are not positive structural limitations and in this sense fail to comply with the requirements of the statute in failing to distinctly claim the actual invention. Note In re Collier, 158 USPQ 266.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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10. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Liprie (5,282,781).

Liprie ('781) discloses applicant's inventive concept. A source wire for localized radiation treatment of tumors comprising: a flexible (see column 5, lines 60+) elongated *stainless steel* (12) tube/housing an outer diameter of 0.018 inches, the tube/housing further comprising a distal end (15) and proximal end (14); a flexible *stainless steel* backbone wire (17) with a distal and proximal end completely disposed within the tube/housing; an iridium-192 radiation source (25) provided in the tube/housing adjacent the proximal end of the flexible backbone wire, the source being two centimeters in length; and a *stainless steel* plug (27) which seals the proximal end of the tube/housing.

Liprie ('781) further discloses that the flexible elongated tube/housing can be constructed of other materials such as titanium or *tantalum* and that the outer surface of the flexible elongated tube/housing is coated with a non-oxidizing agent (i.e., gold). Liprie ('781) also discloses a crimping method of affixing the flexible elongated tube/housing to the backbone wire. Additionally, Liprie ('781) discloses that it is well known within the art to encapsulate the radiation source in a material such as stainless steel (see column 4, lines 10+) to prevent the flaking of the radiation source and to provide such sources with radiopaque markers so as to observe the source with fluoroscopy (see column 16, lines 64+). Also note Liprie ('781) further discloses (see figure 1 and column 9, lines 19+) the inner surface of the proximal end of the housing tube exhibiting a tapered funnel shape for ease of loading the radioactive source within

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said housing tube. Applicant is not claiming the final product/version of the source wire to be funnel shaped.

Note in regard to the final product/version of the source wire Liprie ('781) appears to provide an alternative plug shape (i.e., other than rounded or bullet shaped)(see column 12, lines 21+). Here after the final draw down thin portions of the distal end 15 of the composite source wire 10 are molecularly removed by conventional electroetching to round off or taper the tip. The purpose of the rounded or tapered end of the composite source wire is to ease advancement of the source wire by the loader 35 through an implanted catheter to the tumor site for in vivo localized radiation treatment of the tumor. It appears that such an alternative reads on the embodiment of figure 3.

While patent drawings are not drawn to scale, relationships clearly shown in the drawings of a reference patent cannot be disregarded in determining the patentability of claims. See In re Mraz, 59 CCPA 866, 455 F.2d 1069, 173 USPQ 25 (1972).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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12. Claims 7, 8, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liprie ('781) as applied to claims 1-6, 9-15, 17-25 and 27-31 above, and further in view of either Suthanthiran et al (5,163,896) or Liprie (5,395,300).

As discussed above Liprie ('781) discloses applicant's inventive concept; however, Liprie ('781) does not disclose the rounding of the radioactive core.

Suthanthiran (see abstract and figure 1) teaches the use of rounded titanium encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing radioactive source.

Liprie ('300) further teaches the use of rounded encapsulation of radioactive sources in the same field of endeavor for the purpose of effectively sealing the radioactive source (see figure 1). Additionally note the funnel insertion technique taught in figure 3.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified source wire of Liprie ('781) to have included encapsulation design teachings of either Suthanthiran or Liprie ('300) as such results are in no more than the use of conventionally known radioactive core shapes within the nuclear medicine art.

13. Claims 1-6, 9-15, 17-25 and 27-31 are rejected under 35 U.S.C. 103(a) as obvious over Liprie ('781) in view of Nariciso et al (5,454,794) and/or Ishibe et al (5,230,348).

Liprie ('781) as set forth above discloses applicant's inventive concept; however, Liprie ('781) does not disclose the use of a nickel titanium alloy (Nitinol®) as his housing tube or backbone wire material.

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Liprie ('781) discloses that the flexible elongated housing tube and backbone wire can be constructed of *stainless steel* or other materials such as *titanium* or *tantalum*.

Stainless steel or *tantalum* are material equivalents for Nitinol® this is evident by Nariciso. Referring to column 3, lines 35-40 Nariciso teaches that deflecting wires can be fabricated from metals having tensile strength and memory to deflect and return to their original position such as Nitinol®, *stainless steel* or *tantalum*.

Further note that Ni-Ti alloys (i.e., Nitinol®) are well known within the medical guide wire art. This is evident by the teachings of Ishibe wherein a superelastic alloy comprising Ni (50-60% (preferably 54-57%)) and Ti (40-50% (preferably 43-46%)) provides no stress induced martensitic or martensitic reverse transformations in an elongation range of 0-5%.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have replaced the stainless steel or tantalum alloy of Liprie ('781) with the Nitinol alloy teachings of Nariciso and/or Ishibe, because such results are in no more than the substitution of conventionally known alloys with little or no memory retention.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Keith whose telephone number is (703) 306-5752. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00.

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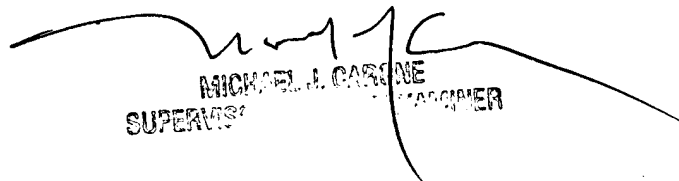
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Carone, can be reached on (703) 306-4198. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7687.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

jwk

August 6, 2002


MICHAEL J. CARONE
SUPERVISOR